

‘*How does society use evidence to judge the risks and benefits of medicines?*’ call for evidence questions

Over the past few years, questions have been raised in both the general and scientific media about the evidence underlying decisions about treatment options (for example the use of statins and Tamiflu). The validity of the different ways of collecting and analysing evidence has been part of this debate. But a wider discussion of issues such as overmedicalisation (or the reliance on prescribing drugs over lifestyle changes) and conflicts of interest in the way that evidence collection is funded and/or analysed has led to wider questions surrounding trust in academic researchers, clinicians, the media and the pharmaceutical industry.

To explore these issues further, the Academy of Medical Sciences is undertaking a project to examine how society uses evidence to judge the risks and benefits of medicinal products, chaired by our President, Professor Sir John Tooke PMedSci. This is an independent project that has the support of the Chief Medical Officer. The British Heart Foundation (through a Strategic Funding Award) and the National Institute of Health Research Health Technology Assessment Programme have kindly provided financial contributions towards this work.

The workstream will consider elements relating to: the strengths and limitations of different sources of evidence used to evaluate the risks and benefits of medicinal products; the ways in which conflicts of interest impact on the validity (or perception of validity) of evidence; the communication of evidence to support informed decision-making; and the perceptions and perspectives of society on scientific evidence (including in the context of shared decision making between patients and their clinicians). The project will not seek to replicate the work performed by the Medicines and Healthcare products Regulatory Agency and the National Institute of Health and Care Excellence. For further information, please visit our website: [http://www.acmedsci.ac.uk/ how-does-society-use-evidence-to-judge-the-risks-and-benefits-of-medicines](http://www.acmedsci.ac.uk/%20how-does-society-use-evidence-to-judge-the-risks-and-benefits-of-medicines).

The remit of this project requires expertise from outside of the Academy and this call for evidence is part of our process of gathering external input. The questions set out in the call for evidence below aim to gather your views on: the strengths and limitations of evidence to evaluate the risks and benefits of medicinal products; effective ways of communicating evidence to various stakeholders; conflicts of interest; and ideas for dialogue around the evaluation of scientific evidence. Your submissions will feed into our initial sub-project on ‘*Methods of evaluating evidence*’, and inform other elements of the workstream.

Selected excerpts may be included in publications arising from the workstream. Please notify us at the time of submission if you do not wish your name or input to be published. We are also happy to receive anonymous submissions.

**Please try to limit your response to no more than 3,000 words, returning the completed form by 21 September 2015 to Dr Claire Cope:** **claire.cope@acmedsci.ac.uk** (020 3176 2164). If you would like to respond but are unable to meet this deadline, please contact the secretariat.

Thank you in advance for taking the time to answer these questions.

*\* Mandatory fields*

\* Name:

\* Job title:

\* Organisation/institution:

\* Email address:

Telephone number:

\* Is this input submitted as an organisational or individual response? Organisation / Individual

\* Are you happy for your response to be published by the Academy? Yes / No

1. **The overarching aim of the workstream is to better understand how society uses evidence to judge the risks and benefits of medicinal products. In your view, what are the key factors underpinning this process that the Academy should consider?**
*Please highlight any related activities that the Academy should be aware of and should seek to engage with.*
2. **When evaluating the risks and benefits of medicinal products, what are the *strengths* of evidence that originates from different sources?**
*Please consider a range of different sources of evidence, including case reports, observational or large databases, randomised clinical trials, meta-analyses, evidence from evolving or novel trial designs, and data emerging from citizen science, among others.
Please provide examples and case studies to illustrate your arguments where appropriate.*
3. **When evaluating the risks and benefits of medicinal products, what are the *limitations* of evidence that originates from different sources?**
*Please consider a range of different sources of evidence as outlined in question 2.
Please provide examples and case studies to illustrate your arguments where appropriate.*
4. **Please provide details of any further examples or case studies that it would be useful for the project to consider.**
*These examples/case studies must relate to medicinal products. We will not consider surgical interventions, medical devices, screening procedures, and so on.*
5. **Please highlight any broadly applicable principles that should govern the presentation, interpretation and weighting of evidence about medicinal products.***We are focussing on principles that support patients, the public, healthcare professionals and the media to better consider the risks and benefits of medicinal products.*
6. **Concerns have been raised about how industry funding impacts on the validity, or the perception of validity, of evidence. For example, the ability of academic researchers funded by industry to remain impartial when evaluating evidence has come into question. How should conflicts of interest be addressed? How important is industry funding in generating and analysing evidence? Other than industry sponsorship, what are other potential sources of conflicts of interest?**
7. **Please outline any past, current or planned initiatives to examine how patients, citizens and healthcare professionals (and those who seek to inform them) evaluate scientific evidence about medicinal products.***Please specify any questions you feel it would be useful for the Academy to explore in our formal dialogue work with patients, citizens and healthcare professionals, and any evidence from previous public dialogue.*
8. **What are the most effective ways of communicating evidence to various stakeholders and engaging with them about such evidence?**
*Please consider a wide range of stakeholders, including patients, the public, healthcare professionals (general practitioners, nurses, pharmacists, clinicians, etc), and the media, among others*.